UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 27 2018

CONTAINS CONFIDENTIAL BUSINESS INFORMATION**

BY REGULAR MAIL AND EMAIL

Sheryl Lindros Dolan, authorized agent for
Hazel Technologies, Inc.
c/o The Acta Group
2200 Pennsylvania Avenue, NW
Suite 100W
Washington, DC 20037

Re: Application for Registration Dated: 04/17/2017
EPA Receipt Date: April 17, 2017
Product Name: Hazel (a.i.: 1-Methylcyclopropene)
EPA File Symbol: 92120-R
OPP Decision Number: 928792

Dear Ms. Lindros-Dolan:

Our records indicate that the decision review period for the U.S. Environmental Protection Agency (Agency or EPA) to make a determination pursuant to section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA), regarding the above referenced application ends on August 31, 2018. The EPA, in meeting its obligation to make a determination within the PRIA decision review period, has determined that your application does not meet the standard for registration under FIFRA and, therefore, cannot be granted at this time.

This letter discusses the factual background and status of your application, summarizes the current data deficiencies, and provides options on how to proceed.

I. Factual Background and Status of Your Application

On April 17, 2017, the Agency received an application from Hazel Technologies, Inc. (HTI) requesting a PRIA B672 code for the registration of an end use product containing the active ingredient 1-Methylcyclopropene, where the source material (technical grade active ingredient (TGAI) or manufacturing-use product (MP)) is not a registered pesticide. The B672 PRIA code states: "New product, unregistered source of active ingredient(s) non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s); requires 1) submission of product specific data, or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data

requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rational explaining why the data requirement does not apply."

It is important to note that when using an unregistered source of an active ingredient, an applicant must address and satisfy the data requirements applicable to the active ingredient source material that is being used to formulate the end use product, as well as the data requirements specific to the end-use product.

On May 1, 2018, the Agency issued a 75-day letter (enclosed) pursuant to 40 CFR §152.105, identifying certain deficiencies in the application. Outstanding deficiencies related to [redacted] data on the proposed end-use product (EP) and the active ingredient source material. At the request of HTI, the Agency held a teleconference on May 3, 2018, with HTI to discuss the content of the 75-day letter. During the teleconference, the Agency informed HTI that to satisfy [redacted] data requirements for the proposed product, HTI could cite non-compensable or compensable data for a similar registered product containing an active ingredient concentration comparable to the one in HTI's product along with a bridging argument for why the data are sufficient. The Agency further advised that if HTI could not address the [redacted] data requirements with existing acceptable data, then HTI would be required to conduct its own study(ies). These data are required for the proposed product because, based on information provided in HTI's application - including on the proposed label, there is a likelihood of [redacted] 1-Methylcyclopropene gas [redacted] such [redacted]

On May 30, 2018, HTI submitted a response to the 75-day letter. Although the response adequately addressed some of the data deficiencies identified in the 75-day letter, the application remains deficient. Section II of this letter contains a description of the specific deficiencies preventing the Agency from proceeding with its review of the application.

II. Summary of Remaining Deficiencies

The deficiencies identified in the Agency's review of your application are described below:

- [redacted] - HTI's response satisfies all [redacted] data requirements for the end use product. The response also satisfies the [redacted] data requirements for the unregistered source material [redacted]

  As noted at 40 CFR 158.2050 (under the table for biochemical data requirements, guideline 870.1300, footnote 3), "acute inhalation toxicity (rat) data are required on the proposed TGAI/unregistered source and the end use product when the pesticide, under condition of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate) unless it is a straight chain lepidopteran pheromone. HTI's proposed product - when activated will result in a gas and [redacted].

  To satisfy the [redacted] guideline data requirements for the TGAI/unregistered source (Guideline 870.1300), HTI [redacted] in the agency's database [redacted]. The [redacted] was conducted using a test substance containing [redacted] 1- Methylcyclopropene and as noted above, the cited study is acceptable for satisfying the [redacted] data requirements on the end use product proposed in your

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application. However, because the [redacted] tested [redacted] active ingredient, it cannot be [redacted] support the unregistered TGAI/source material which contains [redacted] active ingredient.

Because the [redacted] than that in the end use product, the data/information submitted/cited to satisfy the [redacted] guideline data requirement on the source material needed to have included representative [redacted] data/information on a [redacted] This information is absent from HTI's response.

Absent this data/information, the agency cannot make a determination relative to the [redacted] of the proposed [redacted] and therefore cannot move forward with its hazard assessment of the proposed product.

NOTE: If HTI choses to generate data to address this deficiency, please note that the agency has a process for reviewing any study protocol before HTI commences testing.

- To address the [redacted] data requirement on the unregistered source material, HTI's rationale for [redacted] to [redacted] of exposure is insufficient. [redacted] information about [redacted] that is sufficient to demonstrate that 1-Methylcyclopropene will [redacted] the same through the [redacted] Without this information, the Agency is unable to proceed with its review.

- The new data submitted for [redacted] is unacceptable. The study submitted [redacted] and [redacted] to the 14 days required in OPPTS 830.6313 Stability Test Guidelines. The submitted information does not allow the agency to determine the [redacted] 1- Methylcyclopropene gas will be [redacted] at the [redacted] directed on the label for your proposed product. Additionally, the [redacted] measured in the submitted study does not provide the agency with the information needed to determine if there is a [redacted] of the product at the [redacted] directed on the proposed label. A [redacted] or [redacted] is required in order for the agency to assess [redacted] of HTI's proposed product.

- HTI's [redacted] for the end use product did not address the data requirements for [redacted] As such, these data requirements remain outstanding and must be addressed.

As the Agency is unable to complete its review of your application, it is possible that additional deficiencies will be identified upon further review.

III. Options Going Forward

Although this concludes the EPA's PRIA review of your application, this determination is not a denial of your application pursuant to section 3(c)(6) of FIFRA. You have the following four options:

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1. **Resolve the Issues**. You may resolve the issues identified in this letter by submitting the information/data/studies by: 11/12/18. or an explanation of why it will take longer to correct the deficiencies, including your written commitment and schedule to respond to the deficiencies. The EPA will then continue to diligently work with you in resolving the deficiencies without a PRIA decision due date.

2. **Do Nothing**. If you do not respond to this letter, the EPA will administratively withdraw your application on: 11/12/18. Since a fee was paid, the EPA will provide any applicable refund as soon as practicable. Once the application is withdrawn, if you decide to pursue this action again, you will need to submit a new application, including either the appropriate fee or 25% or 50% of the fee and a request for a waiver of the remainder of the fee.

3. **Withdraw the Application**. You may withdraw your application. Since a fee was paid, the EPA will provide any applicable refund as soon as practicable. Once the application is withdrawn, if you decide to pursue this action again, you will need to submit a new application, including either the appropriate fee or 25% or 50% of the fee and a request for a waiver of the remainder of the fee.

4. **Request a Denial**. Although this determination is not a denial under section 3(c)(6) of FIFRA, you may request that the EPA issue such a denial by responding to the Agency prior to: 11/12/18. The EPA will then initiate a denial process, based upon the record before the Agency as of the date of this letter, as described in section 3(c)(6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and the opportunity for a public hearing.

If you have questions concerning or a response to this letter, please contact Cheryl Greene of the Biopesticides and Pollution Prevention Division by phone at (703) 308-0352 or via email at greene.cheryl@epa.gov.

Sincerely,

Richard P. Keigwin, Jr.
Director
Office of Pesticide Programs

Enclosure – 75-Day Deficiency Letter (dated May 1, 2018)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 1, 2018

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BY REGULAR MAIL AND EMAIL

Sheryl Lindros Dolan, authorized agent for
Hazel Technologies, Inc.
c/o The Acta Group
2200 Pennsylvania Avenue, NW
Suite 100W
Washington, DC 20037

Subject: 75-day Deficiencies: Product Chemistry (40 CFR § 158.2030),. Mammalian Toxicology (40 CFR § 158.2050). Residue Information (40 CFR § 158.2040).
Application for Registration Dated: April 17, 2017
EPA Receipt Date: April 17, 2017
Product Name: Hazel (a.i.: 1-Methylcyclopropene)
File Symbol:92120-R
OPP Decision Number: 928792

Dear Ms. Lindros-Dolan:

The U.S. Environmental Protection Agency (EPA or Agency) has received and begun its in-depth review of the subject application and has determined that it is incomplete and that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR § 152.105.

At this time, the EPA has identified the following deficiencies in its review of the subject application:

1. **Product Chemistry** [redacted] - All product chemistry data requirements have been adequately addressed through the submitted MRIDs, with the exception of:

[redacted]

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You must adequately address these data requirements for the proposed product.[1] If you are working to address the requirements you must provide a date for when you intend to submit the data/information.

2. Human Health Toxicity

[redacted]

The MRIDs cited to fulfill the acute toxicology requirements are unacceptable [redacted] [redacted] of 1-MCP in the cited studies is [redacted] of 1-MCP in the proposed end use product EP ([redacted] 1-MCP) and [redacted] ([redacted] 1-MCP).

You must provide acute toxicity data/information that reflects the [redacted] of the [redacted] of active ingredient formulated into the proposed product for the Agency to proceed with its review.

[redacted]

In response to the [redacted] data deficiency, Hazel cites an [redacted] study [redacted] in [redacted] data requirement. This response is unacceptable for the following reasons:

a. The cited study is unacceptable [redacted] with [redacted] of the test substance is [redacted]

b. Additionally, the [redacted] of the proposed EP are potentially [redacted] information was provided on the [redacted] of 1-MCP on fruits and vegetables.

c. Further, [redacted] of Hazel [redacted] from the information on the [redacted] was provided in your response.

Therefore, the supporting rationale for the [redacted] is not adequate to fulfill the [redacted] data requirement and is considered

[1] A data requirement must be addressed with one of the following options:

a. Conduct and submit a guideline study to fulfill the data requirement(s) or;
b. Request a waiver for the data requirement(s). (Note: A waiver means that you are requesting to NOT address the data requirement because the data requirement is not applicable because of x,y,z reasons. You MUST state the reason(s) why the requirement is not applicable) or;
c. Address the data requirement(s) by way of a citation(s) to a study(s) from the open scientific literature. The study should be conducted using either the test substance or a substance that is chemically and structurally similar to the test substance. In addition, you must provide a valid scientific rationale as to the findings of the study and a bridging argument. The bridging argument is a rationale that provides the reasons why the study can be bridged to satisfy the data requirement for the test substance. A copy of the published literature upon which you are relying must be provided.

unacceptable. You must address this deficiency before the agency can proceed with its review of your application.[1]

C. [redacted]

In response to the [redacted] deficiency. Hazel cited an [redacted]. and [redacted] the 90-day dermal toxicology data. The cited studies are unacceptable [redacted] of the test substance is [redacted]

The Agency acknowledges that the proposed EP use pattern does not include purposeful application to [redacted] the EP is not to be removed from the sachet, the [redacted] of exposure, and the a.i. is a gas at room temperature, thus, the potential for repeat occupational handler [redacted] is highly unlikely. [redacted] if the active ingredient is known or expected to be [redacted]

Therefore, the supporting rationale for the [redacted] data requirement is not adequate to fulfill the [redacted] data requirement and is considered unacceptable. You must correct this deficiency in order for the agency to proceed with its review of your application.[1]

[redacted]

To fulfill the [redacted] data requirements Hazel cited [redacted] studies [redacted].

a. The [redacted] described in [redacted] is not considered acceptable [redacted] You must adequately fulfill this data requirement.[1]
b. The study detailed in [redacted] is considered not acceptable [redacted] 1-MCP, which is [redacted] in the 1-MCP [redacted] or Hazel [redacted] You must adequately fulfill this data requirement.[1]
c. The [redacted] is considered acceptable to [redacted] and the study was conducted in accordance with [redacted] The study results indicate that 1-MCP [redacted] Furthermore, there was no indication that 1-MCP is [redacted] according the publicly available databases (IARC, NTP, ACGIH, and OSHA).

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3. Other Deficiencies

1. You have identified [redacted] and stated that it is [redacted] however, an [redacted] was provided to determine if this was an [redacted] You must provide this information in order for the agency to proceed.

Further review of your application and your response to the deficiencies listed above may identify additional deficiencies and you will be so informed.

4. FIFRA Section 33/PRIA

This application is also subject to a deadline for making a determination on this application under FIFRA Section 33, Pesticide Registration Service Fees, established under the Pesticide Registration Improvement Act of 2003 (PRIA). The time frame for the EPA to make a determination on this application ends on: 06/08/2018. Because the deadline for the EPA to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a New Due Date and Resolve the Issue.** You may work with us to establish a new Section 33/PRIA deadline that allows for an appropriate response to the 75-day letter. If you choose this option, you need to contact the EPA no later than: **May 25, 2018**, to discuss a time frame that allows you to address the deficiencies listed above and the EPA to make a regulatory decision.

2. **Withdraw the Application.** Alternatively, you may notify us no later than: **May 25, 2018**, that you are withdrawing your application. As discussed previously in this letter, withdrawal concludes the EPA's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid, the EPA will provide any applicable refund as soon as practicable.[2]

3. **Not Respond.** If the EPA does not hear from you by: **May 25, 2018**, the Agency, in meeting its obligation under Section 33/PRIA, may issue a determination to not grant your application. While a determination to not grant an application would allow the EPA to have met its obligation under Section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to Section 3(c)(6) of FIFRA or withdrawal of the application. Thus, the EPA will continue to diligently work on any such application as long as the EPA receives a response to a deficiency notice within the 75 days described previously in this letter.

Please respond to this letter by: **May 25, 2018**, by contacting Cheryl Greene by telephone at (703) 308-0352 or via email at greene.cheryl@epa.gov.

[2] See https://www2.epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula for more information on refunds.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs